



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. FDA-2012-N-0447]

Antimicrobial Animal Drug Sales and Distribution Reporting; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the advance notice of proposed rulemaking that appeared in the Federal Register of July 27, 2012. In the advance notice of proposed rulemaking, FDA requested comments regarding potential changes to its regulations relating to records and reports for approved antimicrobial new animal drugs. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: The comment period for the advance notice of proposed rulemaking that published July 27, 2012 (77 FR 44177) is extended. Submit written or electronic comments by November 26, 2012.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2012-N-0447, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets

Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2012-N-0447 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Request for Comments” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 27, 2012 (77 FR 44177), FDA published an advance notice of proposed rulemaking with a 60-day comment period to request comments regarding potential changes to its regulations relating to records and reports for approved new animal drugs. FDA is considering revisions to this regulation to incorporate the requirements of section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA 105). The Agency is also seeking public comment on how best to compile and present the summary information as directed by ADUFA 105, and on alternative methods available to the Agency for obtaining additional data and information about the extent of antimicrobial drug use in food-producing animals.

The Agency has received requests for a 60-day extension of the comment period for the advance notice of proposed rulemaking. The requests conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the advance notice of proposed rulemaking.

FDA has considered the requests and is extending the comment period for the advance notice of proposed rulemaking for 60 days, until November 26, 2012. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

II. Request for Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify

comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: September 20, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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